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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,227	10/03/2003	Hiroaki Ito	053466-0365	8597

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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	**PAPER NUMBER**
1646	
MAIL DATE	**DELIVERY MODE**
03/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/677,227	ITO ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,22-43 and 45-47* is/are pending in the application.

4a) Of the above claim(s) *1-19, 22-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43 and 45-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 January 2009 has been entered.

2. Receipt of applicant's arguments and amendments filed on 1/23/2009 is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 6/14/2007:

(i) the rejection of claims 43-47 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,723,319 ('319) in view of the terminal disclaimer filed 6/14/07.

4. Applicant's arguments filed on 1/23/09 have been fully considered and were non-persuasive. The issues remaining and new issues are stated below.

Claim rejections-35 U.S.C. 112, first paragraph, new matter rejection

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 43, 45-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 43 recites "….an anti-interleukin-6 receptor antibody which binds to interleukin-6 receptor having the following amino acid sequence:

MLAVGCALLAALLAAPGAALAPRRCPAQEVARCVLTSLPGDSVTLTCPGVEPEDNA TVHWVLRKPAAGSHPSRWAGMGRRTLLLRSVQLHD SGNYSCYRAGRPAGTVHLLV DVPPEEPQLSCFRKSPLSNVVCEWGPRSTPSLTTKAVLLVRKFQNSPAEDFQEPCQYS QESQKFSCQLAVPEGD S SFYIVSMCVASSVGSKFSTQTFQGCCILQPDPPANITVTAVA RNPRWLSVTWQDPHSWNS SFYRLRFELRYRAERSKTFTTWMVKDLQHHCVIHDAW SGLRHVVQLRAQEEFGQGEWSEWSPEAMGTPWTESRSPPAENEVSTPMQALTTNKD DDNILFRDSANATSLPVQD S SSVPLPTFLVAGGSLAFCTLLCIAIVLRFKKTWKLRALK EGKTSMHPPYSLGQLVPERPRPTPVLVPLISPPVSPS SLGSDNTSSHNRPDARDPRSPY DISNTDYFFPR (SEQ ID NO: 1)" which language is new matter in the claim, since the instant specification fails to disclose such a limitation. The specification fails to provide proper support for this language in the claims for the following reason:

In the specification, page 8, lines 36-37, page 9, lines 1-5, discloses:

For example, human IL-6 receptor used as a sensitizing antigen for obtaining an antibody can be obtained using the IL-6 receptor gene sequence/amino acid sequence disclosed in European Patent Application EP 325474, and mouse IL-6 receptor can be obtained using that disclosed in Japanese Unexamined Patent Publication (Kokai) 3(1991)-155795.

The specification does not disclose the specific limitations as recited in claim 43. Furthermore, it is unclear which sub-unit of the IL-6 receptor the disclosed amino acid sequence encompasses. Is it the IL-6 receptor α-chain (CD126) or the IL-6 receptor β-chain (gp130) (CD130)?

Claim rejections-35 USC § 112, scope of enablement

5b. Claims 43, 45-47, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating inflammatory bowel disease by administering an effective amount of monoclonal antibody, PM-1 or MR16-1 against the human IL-6 receptor, does not reasonably provide enablement for a method of treating all inflammatory diseases by administering "all" interleukin-6 receptor antibodies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

This rejection is maintained for reasons of record set forth at pages 3-7 of the previous Office action (12/5/2006), page 3 of the previous Office action (8/15/07), pages 2-9 of the previous Office action (1/15/08) and pages 2-5 of the previous Office action (7/25/08).

Applicants argue that it is clear that the PTO considered that claim 43 read not only on antibodies against the IL-6 receptor, *per se,* but also gp 130 *(see* rejection under 35 U.S.C. §§ 102, 103). To clarify that claim 43 concerns only antibodies against the human IL-6 receptor, *per se,* claim 43 has been amended to recite that the antibody binds to interleukin-6 receptor having the [amino acid sequence of SEQ ID NO: 1]" SEQ ID NO: 1 is distinct from the sequence of gp130. However, contrary to Applicants arguments, the amino acid sequence inserted into claim 43 is new matter in the claim and therefore, this rejection is maintained for reasons of record.

Claim rejections-35 USC § 112, second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6a. Claims 43, 45-47, are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43, line 3, is vague and indefinite because it recites "…having the following amino acid sequence…". It is unclear if the amino acid sequence is that of the IL-6 receptor antibody or the IL-6 receptor. Furthermore, it is unclear whether "having" is open or closed language.. The conventional open language is "comprising" and the conventional closed language is "consisting of".

Claim 43, last line, is vague and indefinite because it recites "the biological activity of IL-6". There is insufficient antecedent basis for this limitation in the claim.

Claims 45-47 are rejected as vague and indefinite insofar as they depend on the above rejected claims for their limitations.

Claim rejections-35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7a. Claims 43, 45-47, are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 96/38481.

This rejection is maintained for reasons of record set forth at pages 12-13 of the previous Office action (12/5/2006), pages 4-5 of the previous Office action (8/15/2007), pages 10-11 of the previous Office action (1/15/08) and pages 5-6 of the previous Office action (7/25/08).

Applicants argue that pending claim 43 is drawn to an anti-interleukin-6 receptor antibody that binds to an interleukin-6 receptor having an amino acid sequence of SEQ ID NO: 1, the human IL-6 receptor is distinct from gpl30, and so Burstein's disclosure of antibodies against gp 130 cannot anticipate the present claims. However, contrary to Applicants arguments, the addition of SEQ ID NO:1 to claim 43 is new matter in the claim. Furthermore, it is unclear whether SEQ ID NO:1 is the amino acid sequence of IL-6 receptor β (gp130) or the IL-6

receptor α subunit (CD126) and therefore this rejection is maintained for reasons of record.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8a. Claims 43-47 are rejected under 35 U.S.C. § 103 as being unpatentable over WO 96/38481 in view of Queen et al. (U.S. Pat No. 5,530,101).

This rejection is maintained for reasons of record set forth at pages 13-14 of the previous Office action (12/5/2006), pages 5-6 of the previous Office action (8/15/2007) and pages 12-13 of the previous Office action (1/15/08), and pages 7-9 of the previous Office action (7/25/08).

Applicants argue that neither Burstein nor Queen describe an anti-interleukin-6 receptor antibody which binds to interleukin-6 receptor having an amino acid sequence of SEQ ID NO: 1, because the combination of references does not teach all elements of the claims, the claims are not obvious, and *even if the* combination of references did teach this missing element, there would be no obviousness because Burstein teaches away from the present invention by teaching that targeting gp 130 has numerous advantages over targeting the IL-6 receptor. However, , contrary to Applicants arguments, the addition of SEQ ID NO:1 to claim 43 is new matter in the claim. Furthermore, it is unclear whether SEQ ID NO:1 is the amino acid sequence of IL-6 receptor β (gp130) or the IL-6 receptor α subunit (CD126). Since the Burstein reference teaches targeting gp130 with monoclonal antibodies to treat inflammatory bowel disease, and Queen teaches the production of humanized antibodies, the claimed references render obvious the claimed invention and this rejection is maintained for reasons of record.

Conclusion

No claim is allowed.

Claims 43, and 45-47, are rejected.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1646